HB 615: Cancer Clinical Trials
Draft Study Report

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A. INTRODUCTION

With the passage of HB 615, the 2011 Legislature directed the Office of the Commissioner of Securities and Insurance (CSI) to study issues related to the equitable treatment by insurers for cancer patients seeking to participate in cancer clinical trials.

HB 615 directs CSI to:

- Convene an advisory committee of representatives of insurance, reinsurance, and self insurance offerors in Montana, as well as patients, health care advisors, providers, and administrators;
- Assess whether violations of Montana statutes are occurring related to this denial of care or ineligibility of coverage and take appropriate action if any are found;
- Review a selection of other states' policies related to required treatment of cancer routine care coverage for insureds undergoing clinical trials; and
- Summarize and present findings and recommendations to the Children, Families, Health and Human Services Committee on or before March 31, 2012.

HB 615 directs the advisory council to:

- Evaluate the causes of the routine care coverage denials or exclusion for patients recommended for participation in cancer clinical trials;
- Indentify necessary federal policy changes to address denials or exclusion for the purchasers of ERISA-regulated health care plans;
- Define routine care for cancer patients undergoing clinical trials; and
- Make findings and recommendations to address the above items.

B. BACKGROUND ON INSURANCE COVERAGE FOR CANCER PATIENTS ENGAGED IN CLINICAL TRIALS

1. Description of the problem

Some cancer patients in Montana and around the country who have private insurance coverage find that treatment of their routine care is not covered when they join or consider joining cancer clinical trials. The sponsor of a clinical trial, usually the federal government or a pharmaceutical company, pays for the new treatment or device being tested. If the patient is on Medicare, the plan picks up the cost of the routine care—radiation, chemotherapy, etc.

Private insurance companies or plans, however, often consider the entire treatment during the period of the trial to be "experimental or investigational" and judge it to have a potential negative impact on the cost of routine care. While coverage for cancer treatment is common in health plans, exclusions for "experimental or investigational" treatments are also common. A company's decision to deny a claim on that basis relies on their interpretation of what "experimental and investigational" means. There is not a uniform definition.

Generally, a patient may appeal that decision. CSI would assist any patient who files a complaint alleging a plan's failure to pay a covered benefit whether or not a clinical trial is involved. An expedited appeals process would allow for timely resolution based on the medical necessity of the treatment as reviewed by external medical reviewers. If more patients filed appeals and involved CSI, there would be more clarity on the issue of coverage of routine care.

There are many reasons patients may not file appeals. Primary among them is that they are sick and wish to use their remaining energy focusing on their health and their family's needs, not on their insurance coverage. Anecdotal evidence suggests that the barriers encountered in accessing trials may occur much earlier than the formal appeals process. Initial conversations between parties that may not have access to full information may screen out some patients. There may not be complete understanding that the request is for "routine care" not for the "experimental care" being that is the subject of the trial. Past denials by one payer in a particular situation may lead to patients or providers to make incorrect assumptions about future actions by the same or other payers.

Many states and the federal government define "routine care" for cancer patients and require coverage. Those definitions generally say that routine care is the care a patient would get in the absence of a trial. In practice, however, that care can vary widely based on how a patient responds, the types of complications that arise, and the speed at which the disease progresses.

When a trial is added to that mixture of variables, it is difficult, if not impossible to determine whether the trial procedure is negatively impacting the cost of the overall treatment. Complications that arise may be a result of the trial, but they may not. Complications arise in

many patients whether or not they are participating in a trial. Recent studies show that trials do not add to the cost and in some cases may reduce costs. When the trial yields a positive medical result, the cancer patient may live longer and continue to need expensive treatment, or may no longer need the expensive treatment, impacting the overall cost of that patient. Measuring the long-term benefits of new treatments that have positive impacts on population health and lower costs over time is difficult to calculate.

The denial of treatment is difficult for patients and their families who believe the trial provides an opportunity to increase the quality or length of life. Most often those patients do not have the energy to appeal their insurance plan's decision to deny courage of the routine care. Those with strong advocates or unusual perseverance may have better success, leading to inequities in treatment.

Limits on access to clinical trials also concern oncologists, researchers and policy makers who understand the importance of clinical trials for the advancement of treatment and potential for finding cures for illnesses that take a heavy toll on the population, social structures, and public resources.

2. Montana research on coverage of routine care during clinical trials

The Office of the Commissioner of Securities and Insurance has broad authority to collect data from insurance companies under its regulatory authority. Absent a legal mandate for insurance companies to specifically cover routine care during clinical trials and absent a requirement that CSI collect the data, the office has not used its resources or authority to request information from insurance companies in regard to this issue. Tracking actual denials and appeals would be feasible, but may be of limited value. Council members acknowledged that limited access to trials probably occurs more informally. CSI could use its existing authority to request additional data for the purpose of making a data-driven assessment of the extent of the problem in Montana.

The Montana Cancer Consortium is a nonprofit organization whose mission is to bring "state of the art" cancer treatment to Montana through clinical trials sponsored by the National Cancer Institute (NCI). The group works with oncologists across the state to manage grants from NCI for clinical trials. The Consortium does not track denials of coverage for routine care of patients interested in participating in clinical trials.

Two members of the Cancer Clinical Trials (CCT) Advisory Council provided information they could access to the council. As one of the leading clinics conducting trials sponsored by the National Cancer Institute (NCI), Billings Clinic has been tracking clinical trial information for about four years. Offering clinical trials is part of their mission statement. As of 2012, cancer centers are required to have 4% of their patients on clinical trials for American College of Surgeons' Commission on Cancer accreditation. The clinic has been putting approximately 10%

of their patients on trials in all four phases for the last 6 years, relying in some measure on federal and state programs such as Medicare as well as patients without insurance, who qualify for the clinic's assistance plan. In 2010 and 2011, the clinic offered clinical trial participation to 435 patients of the 2000 screened for clinical trials. Of those offered a clinical trial, 294 were enrolled and 141 declined. Of the 141 who declined, 30 were insurance coverage denials, 70% of which were denied because of the plan policy.

New West Health Services reported progress with their fully-insured plans related to clinical trials in the last several years, including a prior review procedure with Billings Clinic. Following successful review of the trial protocol, subsequent patients are approved in advance. They have a list of 20 trials, mostly in phase three, that have been approved. NWHS reported that they received 85 requests for participation in clinical trials from 2003-2011 and approved 72% (61) of them. Thirteen were with self-funded plans and these were generally for phase three trials. Of the 24 that were denied, 8 were with self-funded plans, and 5 were related to quotes of non-coverage for self-funded plans, so these never made it to medical review in 2003. The majority of the trial care that was denied was for those trials in phases one and two. Many insurance plan documents describe these early phase trials to be "experimental" and therefore are not generally covered.

3. Anecdotal stories from patients and providers in Montana*

Several Montanans testified at the 2011 legislative session about their experience with coverage difficulties when considering clinical trials. That testimony is archived on the legislative web page for the House and Senate hearings. CCT Advisory Council received public comment from patients and families during the course of the study. Two patients on the Council offered their experiences. Both were in the same self-funded government plan.

One of them experienced a trial that included a treatment considered to be outside of routine care for his very aggressive cancer. He believed his self-funded insurance plan thought the extra treatment had the potential of interfering with the routine treatment and thus denied coverage of all treatments. Because he was given less than a year to live, he went ahead with the trial under coverage from a government-provided second insurance. He was eventually told that his first insurance would cover routine care on the condition that if anything else came up it wouldn't be covered.

Another patient described his experience with his insurance company. He felt he was up against a stone wall, even though his doctor determined him to be a perfect candidate for a clinical trial that would extend his life. He said the CSI office doesn't get more complaints because so often when people get in that position they don't know what to do next. He elaborated on all the actions he took, including calling the members of the board of the insurance company, until the trial was approved.

4. Current practice by insurers in Montana

Insurance companies consider payment of routine patient costs of those hoping to enter clinical trials on a case-by-case basis. A company may cover routine care after consideration of the trial protocol. Or, they may deny coverage, generally based on a plan's exclusion of "experimental and investigational" treatment. Under most plans patients have the opportunity to appeal the decision to deny coverage.

Many companies also administer self-funded plans for large employers. The contractual agreement in those plans will govern when there is an appeal of their decision to deny coverage. The initial decision to deny is generally based on the company's policies and its definitions regarding "medical necessity" and "investigational and experimental."

5. The issue across the states and how states have responded

It is clear that other states consider the coverage of routine care for cancer patients undergoing clinical trials to be of concern; since 1995, 34 states and Washington, D.C have passed laws or implemented agreements requiring coverage. Following the example of the states, Congress included a provision requiring such coverage under the Patient Protection and Affordable Care Act (ACA) in 2010. Rules implementing the section are anticipated in the coming year, but have not yet been available for examination by the CCT Advisory Council. Medicare has required coverage since at least September 2000 and Medicare's National Coverage Decisions (NCD) was considered by the Advisory Council.

Various state laws and compacts were considered by CSI staff and the CCT Advisory Council in the course of the study. Links to sites that report on state laws, and several examples of laws and agreements are available on the CSI web page at http://www.csi.mt.gov/commcorner/Cancer/CancerResources.asp

6. History of the 2007 effort in Montana

SB 428, requiring coverage of routine costs for cancer patients in clinical trials, was introduced during the 2007 Montana Legislative Session. The bill passed the Senate, but was tabled in the House with the understanding that cancer care providers, payers, and patient advocates would work toward resolving this important health care issue. A collaborative consensus solution was to be formulated by those most involved in the issue.

The resulting Montana Working Group to Improve Access to Clinical Trials was a consortium of the major stakeholders in the care of Montana's cancer patients. The charge of the group was to improve access to clinical trials by undertaking the following:

a. To define routine care
b. To clarify clinical trial terminology

c. To develop and implement operational processes for smooth enrollment and continuation of participation
d. To educate impacted parties about the agreement and help implement it

At one point during the process, the working group described its purpose and activities in this way:

> "The Montana Working Group to Improve Access to Clinical Trials believes this agreement would improve research study recruitment and Montana's cancer patients' access to clinical trials as a treatment option without risk of personal financial burden. Cancer clinical trials provide outcomes data necessary to assess medical practice and build on evidence based, value driven health care. Scientific oversight helps to focus rational decision making within these studies. Montana healthcare payers could benefit from the advancement in science, [the] avoidance of useless treatment, and [the] continuous quality improvement cancer care clinical research provides.
>
> The goal of this agreement is to increase participation in select cancer-related clinical trials by making payment for services provided within the context of clinical trials …predictable. After serious consideration of these concerns and discussion of the rationale for supporting clinical research efforts in Montana, the group agreed that health plans* should be willing to provide coverage for the routine care costs of patient participation in approved clinical trials."

Three subcommittees of the working group were established on June 14, 2007 and assigned to draft portions of a voluntary agreement that would provide the framework for coverage of patient care costs for those enrolled in clinical trials within the scope of the individual's benefit plan:

a. Definitions workgroup: Draft the definition of routine care and clarification of clinical terminology.
b. Operations workgroup: Draft guidelines and operational processes
c. Implementation workgroup: Draft steps for targeted statewide education and implementation.

Draft language for a "consensus agreement" on definitions was written up in October 2007, but consensus was not reached. The effort was abandoned shortly thereafter. Several members of the current CCT Advisory Council served on the 2007 working group and lent their historical perspective to the process.

7. How this "study" is different than the 2007 effort

The informal process in 2007 was directed at reaching a "consensus agreement," following failed legislation. It involved negotiation between stakeholders with the hope of an outcome that reflected an agreement among those stakeholders that would then be implemented voluntarily.

The current effort is the result of the passage of HB 615 and is designed to be a "study" not an informal "negotiation." The Office of the Commissioner of Securities and Insurance is directed to conduct the study and provide necessary resources. The outcome is a report on the recommendations and findings of an official advisory council to the Commissioner.

The process of the HB 615's study, however, did result in a negotiated definition between council members on the definition of routine care during clinical trials. The Council believes there is more work to be done to educate providers, insurers and employers about the definition, to train providers on the role of CSI in coverage denial appeals; to generate support for legislation to formalize the definition, and to get agreements from self-funded plans. The Commissioner has agreed to continue to facilitate additional meetings of the advisory council for those purposes.

8. How the climate has changed since 2007

The context in 2011-12 was more conducive to progress on the issue of coverage for cancer patients' routine care while accessing a clinical trial. The Patient Protection and Affordable Care Act passed Congress in March 2010. One of its provisions requires the coverage of routine care costs for cancer patients in clinical trials. The provision goes into effect January of 2014. The U.S. Department of Health and Human Services is expected to draft rules on this provision in the coming years. The National Association of Insurance Commissioners (NAIC) was asked to recommend model language for those rules, and has placed it on the agenda for their Regulatory Framework (B) Task Force meeting in the fall of 2012. Commissioner Lindeen serves on that committee. Commissioner Lindeen also serves as the Secretary-Treasurer of the NAIC.

In addition, new scientific studies are available about the costs and benefits of clinical trials and were examined by council members. Providers and payers alike are exploring new models for delivering and paying for care, improving health outcomes, and using electronic medical records. Commissioner Lindeen facilitates one such effort— the Montana Patient-Centered Medical Home Advisory Council. Finally, consumers are more engaged in the public discourse around health care. All these factors have helped stimulate more collaborative efforts, resulting in the following findings and recommendations.

C. FINDINGS BY CSI ON STUDY ACTIVITIES DIRECTED TOWARD CSI

1. Convene an advisory committee of representatives of insurance, reinsurance, and self insurance offerors in Montana, as well as patients, health care advisors, providers, and administrators.

CSI made a general call to parties that might be interested in serving on an advisory council in June, 2011. CSI staff examined the responses to see how they fit the representation required in the law, spoke with participants to ascertain their level of interest, contacted others to fulfill the requirements, and announced the final council participants on August 12, 2011. Council members are identified on the CSI web site at http://www.csi.mt.gov/commcorner/Cancer/CCTAC0911.pdf

The creation of advisory councils is addressed in 2-15-122 MCA. Their purpose is only to serve in an advisory capacity as defined in 2-15-102, MCA. In short, the law sets out the duties of advisory councils as "furnishing advice, gathering information, making recommendations and …. [not] administering a program or setting policy."

The "advisory committee" addressed in HB 615 is known as the Cancer Clinical Trials Advisory Council. The advisory council serves at the pleasure of the Commissioner and the names of its members have been filed with the governor's office and the secretary of state. The council will exist no longer than two years and the group selected a presiding officer. Official minutes were taken, approved, and posted. Rules of quorum were followed. Except for government employees, members were entitled to pay and expense reimbursement.

The council helped CSI evaluate the causes of the routine care coverage exclusions and denials, indentify policy changes at the federal level necessary to address these issues in ERISA-regulated self-funded plans, define routine care for cancer patients undergoing clinical trials, make findings and recommendations to the commissioner for possible resolution of issues identified, and respond to a draft study report.

The council met six times between September 2011 and March 2012, when the final report and recommendations were presented to the Interim Children, Families, Health, and Human Services Committee. Three meetings were held in person in Bozeman and three meetings were held via conference call. The agendas and official minutes of each meeting are available on the CSI website at http://www.csi.mt.gov/commcorner/Cancer/CancerMeetings.asp.

An interested parties list was maintained and its members informed of all meetings, electronic or in-person, and encouraged to give public comment. A public web page was available at the CSI website. It includes additional information about the council's activities, contact information to sign up for the interested parties list, and resources from other states.

2. **Assess whether violations of Montana statutes are occurring related to this denial of care or ineligibility of coverage and take appropriate action if any are found;**

CSI does not currently collect routine data from insurance companies that will allow it to ascertain whether violations are occurring specifically related to clinical trials. Absent individual consumer complaints, or findings in a market conduct examination, CSI does not have knowledge about denials related to clinical trials.

Finding such a denial during a general market conduct examination would be unlikely unless specific intention was directed toward the issue, as only a small sample of cases are examined. Because there is no state law specifically requiring coverage of routine care for patients participating in clinical trials, a market conduct exam is unlikely to make a public finding related to failure to cover routine care during clinical trials, even if it found evidence. This will change with the implementation of federal law in 2014 when the coverage is required. If Montana conformed its law to the federal law, CSI would have the authority to enforce compliance with the federal law's provision requiring coverage of routine care during clinical trials, and access to trials would improve.

Most major medical plans cover cancer treatment and it would be illegal for the plan to fail to provide coverage according to their contract. CSI would assist any patient who files a complaint alleging a plan's failure to pay a covered benefit whether or not a clinical trial is involved. An expedited appeals process would allow for timely resolution based on the medical necessity of the treatment as reviewed by independent medical reviewers. This can occur even if a plan has denied a claim based on an exclusion for "experimental and investigational" treatment. For fully-insured plans, CSI has authority to impose a fine or order payment if the appeal supports the patient's claim.

To date, there has been only one complaint to CSI involving a clinical trial. The patient was covered under an ERISA-regulated, self-funded plan, over which CSI has no regulatory authority. However, CSI was able to help negotiate a solution informally. Under new federal law, states have now been given additional authority to assist with patient appeals under ERISA-regulated self-funded plans, although states cannot enforce federal law without a conforming state law. Further, federal now requires external independent medical review for self-funded plans, if the appeal is not settled. The state already requires this for fully-insured plans.

Given the testimony at the legislature and the experience of members of the advisory council, it is likely that difficulty accessing trials is more widespread than the anecdotal information suggests. It is possible that the limitation on access to clinical trials occurs informally at an earlier stage, with no paper record of the actions. Patients in this situation may not know they can file complaints with CSI; they may not believe filing a complaint would be effective; they

may be too sick to file, or they may simply be unable to successfully negotiate with insurance companies. Providers and patient advocates may also experience many of these barriers. If cancer patient advocates or case managers had additional training on filing appeals and more knowledge about the consumer ombudsman function of CSI, more appeals might be filed, more attention would be paid, and access for patients might improve.

Given this directive in HB 615, CSI is considering whether to ask major insurance carriers to provide information and data that shows they are meeting their contractual obligations to pay for cancer treatment when patients are in clinical trials. Members of the advisory council would be asked to comment on potential questions for a survey. Do we want to recommend that CSI do this survey? If so, CSI could flesh this out with some dates and the council could recommend or review sample questions.

3. **Review a selection of other states' policies related to required treatment of cancer routine care coverage for insureds undergoing clinical trials;**

CSI staff conducted research from readily-available sources to provide a report to the advisory council on other states' policies. The information has been posted on the CSI web page at http://www.csi.mt.gov/commcorner/Cancer/CancerResources.asp
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4. **Summarize and present findings and recommendations to the Children, Families, Health and Human Services Committee on or before March 31, 2012.**

CSI was available at the request of the Children, Families, Health and Human Services Committee to present a final report at the committee's regularly scheduled meeting on March 19 and 20, 2012. In addition, CSI will be available to provide additional reports related to on-going activity, either written or in person, at the request of the interim committee. The advisory council was invited to review a draft report and offer comment to the Commissioner. Members were advised of the presentation of this report to the interim committee.

D. FINDINGS OF THE ADVISORY COUNCIL ON STUDY ACTIVITIES DIRECTED TO THE COUNCIL

1. Evaluate the causes of the routine care coverage denials or exclusion for patients recommended for participation in cancer clinical trials;

Patients, providers and insurers on the advisory council informed other council members of their experience and perspective on the issue. Additional experts and the public were invited to provide information on the problem and potential solutions. Public comment was advertized and taken at each council meeting. Comments were recorded in the official minutes of the Council at the CSI web page at http://www.csi.mt.gov/commcorner/Cancer/CancerMeetings.asp.

At its first meeting, the members of the Council spoke to their perspective on the causes of coverage denials and where they thought problems existed. CSI staff summarized comments in a "Causes of Denial" draft document. Members discussed the document on-line and at the second meeting, and agreed to set it aside until some agreement had been reached on the definition of routine care. At that time council members hoped the "barriers to access" could be addressed alongside potential solutions.

At its forth meeting, the Council considered a revised draft. They decided to distinguish between barriers that could be addressed by education, those that could be addressed by process changes, and those that needed policy changes. The council appointed a subcommittee to work on a statement of barriers. At its fifth meeting, council members acknowledged that many initial barriers identified had been worked through in discussion and mutual education. The council did not finalize the draft document, but elected to summarize their agreements in this report.

Education

Council members understood that other parties did not have the benefit of the education that occurred on the council and would need to be convinced through an educational outreach effort**.** The first set of findings would need to be addressed in such an effort:

Council findings—

a. Oncologists are trained and expected to enroll patients in clinical trials not only to advance treatment for the long term, but to provide the best possible care for their current patients.
b. Clinical trials do not generally add to the cost of patient care, and may as well produce nominal decreases as nominal increases in cost.
c. Patients may or may not be sent out-of-state for treatment, whether or not they are enrolled in a clinical trial, but this generally does not add cost for the insurer or plan.
d. Employer-based, self-funded plans are not regulated by CSI and (except for government plans and MEWAS) cannot be compelled by state legislation. However, self-funded

plans respond to market forces and educational efforts, and should be approached for voluntary compliance, as it will be required in federal law in 2014.

e. Self-funded plans that purchase reinsurance can include a statement of their intent to cover routine care during clinical trials in their Summary Policy Documents and expect reinsurance coverage.
f. With adoption of the recommended definition (see below),
    i. insurers can be assured that routine care is defined and distinct from experimental or investigational treatments, and that coverage for patients enrolled in clinical trials in any phase is the same as that provided patients not in a trial;
    ii. patient and provider confusion about policy language and insurer practice during clinical trials will be addressed;
    iii. insurer concerns about providers recommending coverage for "off label" trials will be addressed;
    iv. patients and providers will be assured that coverage determinations by insurers regarding requests about clinical trials will be more consistent;
    v. more patients can focus on their health, wellness, and family concerns instead of their fears about cost and coverage.

Policy Changes

The council agreed that a clear policy statement needs to be adopted implementing the definition of routine care and clinical trials identified below.

Council Findings—

a. Clinical trials administer experimental new treatments which are paid for by the trial sponsor. Some insurers in some cases consider that the new treatment has the potential to impact routine care administered during clinical trials and may deny coverage for the routine care in addition to the new treatment.
b. Language written in plan documents for exclusion of "experimental and investigational" treatments can lead to initial denial of coverage before being submitted for medical review. A patient, unable to pay for routine care out-of-pocket, may be forced to forgo the most effective course of treatment available.
c. There are not industry-wide, standard definitions of "experimental or investigational" which can lead to inconsistent interpretation and coverage by insurers.
d. The process for patients to appeal coverage decisions is not well-known or consistent with national models. Patients with greater persistence, energy and support are better able to negotiate with their plans to get their requests reviewed.
e. Inconsistencies in these situations can be diminished if insurers and providers adopted a common definition and insurers agreed to cover the routine care.

Process Changes

The council also discussed various processes that might be improved to reduce barriers. They discussed a recommendation that all trial requests be routinely submitted for medical review with the member receiving written notice of the outcome and right to appeal. However, they agreed that if routine care coverage is required, the review would not be necessary.

Council Findings—

a. There would be a smoother, more predictable approval process if insurers had consistent access to summaries of trial protocols for review prior to coverage determination.
b. The process developed between New West Health Services and Billings Clinic for prior approval of particular clinical trials, has resulted in streamlined coverage agreement for patients enrolled in those trials. This process could be replicated by other payers and clinics.
c. Additional collection of data about approvals and denials of routine care during clinical trials is unlikely to yield accurate results and should not be required. The benefit of having more data may not justify the cost of gathering it. It is better to just fix the problem by requiring or agreeing to cover routine care.

2. Indentify necessary federal policy changes to address these issues for the purchasers of ERISA-regulated health care plans;

Experts on the council and CSI staff discussed ERISA-regulated self-funded health plans and federal reform as it relates to regulation of insurance regarding clinical trials. The federal law referred to as the Affordable Care Act requires policy changes for all non-grandfathered plans by January 1, 2014. Comments were recorded, synthesized, and reviewed by the council.

Council Findings—

a. ERISA is a very broad law from the 1970s that relates to many different employee benefits, including pensions, but also relates to health plans that are employer sponsored.
b. State regulation does apply to fully-insured employer-sponsored health plans, but does not apply to self-funded employer-sponsored health plans, except for MEWA's (multiple employer welfare associations).
c. ACA and HIPPA provisions apply to self-funded ERISA-regulated health plans, with some exceptions.
d. Self-funded government plans are not regulated by ERISA or the CSI, but many provisions of HIPAA and the ACA do apply to self-funded government health plans.
e. The NAIC is working on models to incorporate the ACA into state laws, including clinical trials. The new federal law provides an opportunity for the Council to impact federal

regulation or guidance, but state models will not apply to single-employer, self-funded health plans.

f. The NAIC could place a more specific definition of routine care in the NAIC model. The council could provide comments to the NAIC committee who is creating model law.
g. The advisory council or the commissioner could also provide comments on clinical trials to the Center for Consumer Information and Insurance Oversight (CCIIO).

3. Define routine care for cancer patients undergoing clinical trials;

At its second meeting, the Council initiated efforts to narrow its focus and reach agreement on a definition for routine care for cancer patients that will best serve the needs of Montana consumers, providers and insurers. The CSI staff presented definitions contained in numerous other state laws and agreements, in Medicare, and in the Affordable Care Act. One council member drafted another option based on Oregon's model. The council discussed the portion of the 2007 draft statement containing the definition of routine care for cancer patients and generally agreed that the document was needlessly lengthy and outdated. They recommended the council should use a different starting place.

After considerable discussion, the Council voted to use the current federal definition as a starting point for Montana's definition, and discuss clarifications or additions that would further refine the meaning for Montana.

Council Findings—

1. Most definitions of routine care for cancer patients in clinical trials were similar, stating that it was the same care that any cancer patient would receive in the absence of a trial.
2. The federal law provides a floor for state action. A state may not adopt a policy that is less protective than federal law.
3. The definition of routine care cannot be understood and adopted without defining clinical trials.
4. Costs of the experimental treatment in clinical trials must be borne by the trial sponsor.
5. Cost of administering the new treatment alongside the routine care should be borne by the payer.
6. Complications are covered as routine care whether or not a patient is on a clinical trial. Council members agreed it would be nearly impossible to know if a particular complication was caused by the new treatment.
7. The definition in Appendix A incorporates these findings.

E. COUNCIL RECOMMENDATIONS TO THE COMMISSIONER

On Education

1. That CSI provide specific education to cancer clinics in the state about the definition of routine care, the requirements in state and federal law, and the process for patient appeals.
2. That the Commissioner authorize the Council to continue to meet to develop an educational campaign directed toward patients, advocates, providers, and insurers to achieve the understanding developed between parties on the Council.

On State Policy

3. That plan documents and benefit policies be amended to cover routine care for patients enrolled in clinical trials, based on the definition of routine care adopted by the council.
4. That the Commissioner ask the Interim Children, Families, Health and Human Services Committee request legislation adopting the Council's recommended definition of routine care and clinical trials and requiring all plans within the state's jurisdiction to cover routine care.
5. That the Commissioner authorize the Council to continue to meet to draft an agreement for consideration by self-funded plans over which CSI has no regulatory authority. The agreement would incorporate the recommended definition and be presented to self-funded plans for their voluntary compliance, and become effective when the bill is passed and approved.
6. That CSI propose legislation to update Montana's laws on patient appeals to meet national standards. (This needs more discussion, as it was only implied at one meeting)

On Process

7. That CSI ask insurers on the Council to agree on what information they need from providers about the trials and produce a standard request document.
8. That the Commissioner authorize the Council to continue to meet as needed to facilitate discussion between insurers, self-funded plans and providers on the standard request document.
9. CSI should make the document available to all insurers and require its usage.

On Federal Policy

10. That CSI encourage the NAIC and CCIIO to ensure that all group and individual health plans be subject to the same regulations regarding coverage for routine care for patients enrolled in clinical trials.
11. That CSI support an agreement and a legislative resolution encouraging employers who self fund to honor the advisory council process by voluntarily covering routine costs for cancer patients who are participating in clinical trials

On a Definition of Routine Care

12. That Montana's definition be incorporated into Montana law along with a requirement to cover routine care during clinical trials.
13. That an agreement be drafted that recommends self-funded plans cover routine care during clinical trials.
14. That Montana's additions to the definition be presented to the NAIC and CCIIO for consideration in federal guidance on the issue of clinical trials.
15. That routine care during clinical trials for other life-threatening diseases be considered in a similar way to cancer, despite the council's focus on cancer.

Appendix A

COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

‘‘(a) COVERAGE.—

‘‘(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

‘‘(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

‘‘(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

‘‘(C) may not discriminate against the individual on the basis of the individual’s participation in such trial.

‘‘(2) ROUTINE PATIENT COSTS.—

‘‘(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

‘‘(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—
‘‘(i) the investigational item, device, or service, itself;
‘‘(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient;
‘‘(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis; or
“(iv) items or services customarily provided by a clinical trial sponsor.

‘‘(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

‘‘(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

‘‘(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

‘‘(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer.

‘‘(2) Either—
‘‘(A) the referring health care professional is a participating health care provider and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

‘(B) the participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

‘‘(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan’s (or coverage’s) health care provider network unless out-of network benefits are otherwise provided under the plan (or coverage).

‘‘(d) APPROVED CLINICAL TRIAL DEFINED.—

‘‘(1) IN GENERAL.—In this section, the term ‘approved clinical trial’ means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer that is not designed exclusively to test toxicity or disease pathophysiology, that has therapeutic intent, and is described in any of the following subparagraphs:

‘‘(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

‘‘(i) The National Institutes of Health.

‘‘(ii) The Centers for Disease Control and Prevention.

‘‘(iii) The Agency for Health Care Research and Quality.

‘‘(iv) The Centers for Medicare & Medicaid Services.

‘‘(v) cooperative group or center of any of the entities described in clauses (i)through (iv) or the Department of Defense or the Department of Veterans Affairs.

‘‘(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

‘‘(vii) Any of the following if the conditions described in paragraph (2) are met:

‘‘(I) The Department of Veterans Affairs.

‘‘(II) The Department of Defense.

‘‘(III) The Department of Energy.

‘‘(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

‘‘(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

‘‘(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

‘‘(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

‘‘(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.